REMARKS/ARGUMENTS

Rejections under 35 USC 112, first paragraph

In the final Office Action mailed June 16, 2006, claims 1-18, 23-24, and 28 were rejected under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement. Claim 28 has been cancelled without prejudice. It is respectfully submitted that the amendment to claim 1 renders the Section 112 rejection to claims 1-18 and 23-24 moot.

Claim 1 now claims "A pharmaceutical composition comprising metaxalone in a pharmaceutically acceptable solubility-improved form and at least one pharmaceutically acceptable excipient, characterized in that the pharmaceutical composition has enhanced oral bioavailability as compared to the pharmaceutical composition of metaxalone corresponding to New Drug Application No. 13-217 when they are administered to a patient on an empty stomach."

The Examiner has considered the wording "when administered without food to a patient who has fasted" as not complying with written description. Applicants respectfully disagree. The above amendment to claim 1 is made to facilitate prosecution. The expression "administered without food to a patient who has fasted" simply means "administered to a patient ***on an empty stomach***." The specification on page 1, lines 7-10, page 2, lines 20-24, page 5, lines 28-33, and page 6 lines 1-3 describes the composition of the instant invention being given to a patient having an empty stomach. The example on page 9, lines 11-13 exemplifies that the pharmaceutical composition of the instant invention and the conventional pharmaceutical composition of metaxalone available commercially (Skelaxin®) are administered after overnight fast are only illustrative in that they are administered to patients on an empty stomach.

The meaning of "on an empty stomach" is clear to a person of ordinary skill in the art, *i.e.*, when the stomach is substantially empty of food. *See* the enclosed Chapter 63, "Propulsion and Mixing of Food in the Alimentary Tract" in "Textbook of Medical Physiology", A. C. Guyton and J. E. Hall, 10th Edition, 2004, Elsevier, page 728-737 (a copy of which was submitted in a Supplemental Information Disclosure Statement, dated October 13, 2006).

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Thus a person of skill in the art would understand that "on an empty stomach" means, for instance, a condition when food has been digested and the chyme substantially emptied from the stomach. A person of ordinary skill in the art is further aware that, for an ordinary adult, this takes approximately 2-4 hours. Please see "Principles of Anatomy and Physiology", G. J. Tortora and S. R. Grabowski, 9th Edition, John Wiley & Sons, Inc., 2000, page 839-840, and "Remington: The science and Practice of Pharmacy", 20th Edition, Volume II, Editor- A. R. Gennaro, Lippincott Williams & Wilkins, 2001, page 1084-1085 (copies of which were submitted in a Supplemental Information Disclosure Statement, dated October 13, 2006).

The description does not require inclusion of any particular time period because the use of the term administration "on an empty stomach" is common in the art. For example, please refer to "Remington: The science and Practice of Pharmacy", 20th Edition, Volume II, Editor- A. R. Gennaro, Lippincott Williams & Wilkins, 2001, page 1147 (a copy of which was submitted in a Supplemental Information Disclosure Statement, dated October 13, 2006), which recites as below:

> The presence of a large meal in the stomach will delay gastric emptying. If a drug that is absorbed in the intestine is ingested with a large meal, the delay in gastric emptying may result in a delay in absorption of the drug. However, the presence of food in the stomach also has been shown to increase absorption of some drugs. For example, the bioavailabilities of the β-adrenergic blocking drugs, propranolol and metoprolol, are enhanced by the presence of food. Therefore, because of the difficulty in predicting the absorption pattern of a drug in the presence of food, **it is usually advisable to administer drugs when the stomach is empty or 30 min prior to meals;** an exception is with drugs that cause GI irritation and nausea." [Emphasis added].

Thus, the above paragraphs explain how the description requirement for claims 1, 3-18 and 23 is met. Given that explanation, it is respectfully submitted that the specification more than sufficiently demonstrates that applicants were in possession of the invention as claimed at the time the application was filed.

For clarification, claim 1 has been amended to contain the limitation of claim 28, and claim 28 has been cancelled. The Office Action considered claim 28 directed to a composition,

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wherein the bioavailability is characterized in relationship to a New Drug Application (NDA) No. 13-217, as not being in the instant specification and thus rejected as failing to comply with the written description requirement. The specification has been amended to clarify that the bioavailability of the pharmaceutical composition of the present invention was compared to that of conventional pharmaceutical composition of metaxalone available commercially (Skelaxin® (corresponding to New Drug Application No. 13-217, 400 mg tablets). No new matter has been added by this amendment to the specification as shown by the following:

- The only commercially available metaxalone composition at the time the instant application was filed was Skelaxin®, which has NDA No. 13-217, a fact known in the art and available on Orange Book listing.
- Skelaxin® and "commercially available metaxalone composition" have been equated with each other and described throughout the specification.
- The disclosure of Skelaxin® inherently discloses NDA No. 13-217.
- The specification need not provide in 'haec verba' support for the language added to the claim. In order to comply with the written description requirement, the specification "need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the date the applicant had invented what is now claimed." *All Dental Prodx LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779, 64 USPQ2d 1945, 1948 (Fed. Cir. 2002), quoting *Eiselstein v. Frank*, 52 F.3d at 1038, 34 USPQ2d at 1470 (citing *Vas-Cath*, 935 F.2d at 1562, 19 USPQ2d at 1115, and *In re Wertheim*, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976)).

In other words, the term "Skelaxin" is synonymous with the metaxalone of NDA No. 13-217. Applicants have not added new matter, but have merely substituted one synonym for another. The substitution of NDA No. 13-217 is exactly the type of amendment permitted by M.P.E.P. 2163.07 I., which specifies that "a rewording of a passage where the same meaning remains intact is permissible." *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

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See also Scarring Corp. v. Megan (sic, Schering Corp. v. Amgen, Inc.), 222 F.3d 1347, 1352-53, 55 USPQ2d 1650, 1654 (Fed. Cir. 2000) (quoted in the M.P.E.P).

In *Scarring (sic, Schering)*, the original disclosure drawn to recombinant DNA molecules utilized the term "leukocyte interferon." After the filing date, a scientific committee abolished the term in favor of "IFN-(a)," since the latter term more specifically identified a particular polypeptide and since the committee found that leukocytes also produced other types of interferon. The court held that the subsequent amendment to the specification and claims substituting the term "IFN-(a)" for "leukocyte interferon" merely renamed the invention and did not constitute new matter. The present circumstances are precisely aligned with those of *Schering*, and *Schering* thus compels withdrawal of the rejection. *Accord, Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1153-54 (Fed. Cir. 2004) (following *Schering* with approval for the holding that "[b]ecause the amended material is inherently contained in the original application, it cannot constitute new matter").

In *Koito*, a Certificate of Correction was filed that altered the definition of the thickness of the flow channel in the description of the first and second embodiments of the invention. For example, the patent originally disclosed that the second mold cavity section 24 has a thickness G that is at least as thick as the flow channel 26 with thickness H. The certificate of correction then clarified that thickness G is at least as thick as the flow channel 26 minus the first-layer-defining mold-cavity section 22. The effect of this correction was to redefine the flow channel. Before the correction, the flow channel could have been considered to be only the protrusion from the first-layer-defining mold-cavity section 22. After the correction, however, the flow channel was considered to have the depth of that section and the protrusion. The Federal Circuit noted that the original description would have excluded the second preferred embodiment as shown in Figures 4 and 5, because all the claims in the patent require a flow channel that is thicker and wider than the adjacent cavity. The Federal Circuit held that because the amended material is inherently contained in the original application, it cannot constitute new matter. The present case is precisely aligned with *Koito*, and *Koito* thus compels withdrawal of the rejection.

Rejections under 35 USC 102(e)

Claims 1-2 and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,407,128 to Scaife et al. Claim 1 has been amended to include the limitation of claim 2. Claim 1 now claims "A pharmaceutical composition comprising metaxalone in a pharmaceutically acceptable solubility-improved form and at least one pharmaceutically acceptable excipient, characterized in that the pharmaceutical composition has enhanced oral bioavailability as compared to the pharmaceutical composition of metaxalone corresponding to New Drug Application No. 13-217 when they are administered to a patient on an empty stomach." As shown above, the pharmaceutical composition in Scaife et al. corresponds to New Drug Application No. 13-217. The claimed pharmaceutical composition of the present application comprises "metaxalone in a pharmaceutically acceptable solubility-improved form" and "has enhanced oral bioavailability as compared to the pharmaceutical composition of metaxalone corresponding to New Drug Application No. 13-217 [i.e., the pharmaceutical composition in Scaife et al.] when they are administered to a patient on an empty stomach." Scaife et al does not disclose metaxalone in a pharmaceutically acceptable solubility-improved form.

It is respectfully submitted that the statement in the Advisory Action mailed November 17, 2006 that Scaife "teaches a pharmaceutically acceptable form of metaxalone (see col. 2 lines 10-15) with enhanced bioavailability as compared to the commercially available form Skelaxin® (see col. 2 lines 5-35)" is incorrect. The form of metaxalone in Scaife is identical to the commercially available form Skelaxin®:

> FIG. 1 is a plot of the mean plasma concentration of metaxalone in nanograms per milliliter versus the time elapsed from administration of the dosage form. Two (2) plots are shown for the 400 mg dosage form administered with and without food.
>
> SUMMARY OF THE INVENTION
>
> The subject of this invention is the unexpected finding that administration of metaxalone with food increases both the rate and extent of absorption via the oral dosage form in human subjects.

> One aspect of this invention is a method of increasing the bioavailability of metaxalone in a human patient receiving metaxalone therapy wherein the metaxalone is contained in a pharmaceutical composition, which method comprises administering a therapeutically effective amount of metaxalone to the patient with food.
>
> Another aspect of the invention is providing a method of increasing rate and extent of metaxalone absorption as measured by the drug concentration attained in the blood stream over time of a patient receiving, the drug in an oral dosage form which method comprises administering a therapeutically effective amount of metaxalone to the patient with food. (Scaife, col. 1, line 66 through col. 2, line 22).

As described above, the form of metaxalone administered in Scaife is the commercially available form – the only difference is that Scaife teaches that the administration of food with the same form of metaxalone can increase the rate and extent of absorption of the same form of metaxalone in patients than if the same form of metaxalone is administered without food.

As shown above, while Examiner's cited portion of col. 2 of Scaife discloses that the "subject of [Scaife's] invention is the unexpected finding that administration of metaxalone ***with food*** increases both the rate and extent of absorption via the oral dosage form in human subjects" (emphasis added). Scaife is thus antithetical to the claimed invention, which is directed towards a form of metaxalone that has enhanced bioavailability on an empty stomach and that is different from the form of metaxalone disclosed by Scaife.

In other words, Scaife seeks to increase bioavailability of metaxalone in a way that is different from the claimed invention. Scaife uses conventional metaxalone (Skelaxin®). Note that Scaife equates Skelaxin with metaxalone at col. 1, line 9. See also Col. 2, lines 51-55: "The effect of food on metaxalone absorption was identified in a study designed to compare the bioavailability of 400 mg of metaxalone in the formulation the drug product Skelaxin® administered to healthy volunteers with and without food." ." The present invention, on the other hand, concerns a form of metaxalone that is different from the conventional form of metaxalone

In sum, claim 1, as amended, is not anticipated by Scaife et al. As shown below, amended claim 1 is also non-obvious over the prior art, and is therefore patentable. For the same reason claim 1 is patentable over Scaife et al., dependent claim 15 is patentable over Scaife et al.

Rejections under 35 USC 103(a)

Claims 1-15 and 27-28 stand rejected as being unpatentable over Scaife et al. in view of Gilis et al. U.S. Patent No. 6,030,988. Claims 16-18 stand rejected as unpatentable over Scaife et al. as applied to claims 1-15 above in view of Cheng et al. U.S. Patent No. 6,099,859. These rejections are respectfully traversed.

Scaife et al. does not teach "A pharmaceutical composition comprising metaxalone in a pharmaceutically acceptable solubility-improved form and at least one pharmaceutically acceptable excipient, characterized in that the pharmaceutical composition has enhanced oral bioavailability as compared to the pharmaceutical composition of metaxalone corresponding to New Drug Application No. 13-217 when they are administered to a patient on an empty stomach." Neither does Scaife et al. teach "A pharmaceutical composition comprising micronized metaxalone" as claimed in claim 3.

As noted above, Scaife reports experimental results obtained with metaxalone that corresponds to New Drug Application No. 13-217. The way that Scaife seeks to improve bioavailability of metaxalone is to administer conventional metaxalone with food. Scaife says nothing about using a form of metaxalone that is different from that corresponding to NDA 13-217. Indeed, Scaife discloses that providing metaxalone with food is a satisfactory solution to his concerns with bioavailability. One skilled in the art would thereby be taught away from the notion of a form of metaxalone that is different from the conventional form.

Gilis et al. does not remedy the deficiencies in Scaife et al. The Office Action acknowledges that Gilis et al. does not teach a pharmaceutical composition comprising metaxalone, but contends that Gilis et al. teaches that a micronized formulation of any drug results in enhanced bioavailability. This contention is incorrect.

Gilis et al. discloses that, instead of using cisapride monohydrate, if solid oral dosage forms of certain cisapride salts like tartrate are used, the formulation can be taken independently from the meal. Gilis et al. relates to use of certain salt forms of cisapride like tartrate, sulfate and citrate. A person of ordinary skill in the art would know a "solubility-improved form of metaxalone" can not be a tartrate, sulfate or citrate salt of metaxalone because formation of such salts with metaxalone is not possible. Thus Gilis et al. does not teach the preparation of a "solubility-improved form of metaxalone" in the form of a metaxalone salt. Also with reference to particle size modification to obtain a solubility-improved form of cisapride or by inference metaxalone and therefore enhanced bioavailability, the examples in Gilis et al. disclose cisapride tartrate formulations without mentioning the particle size. Example 14 on dissolution studies and Example 15 on bioavailability studies do not show the effect of particle size on bioavailability. These comparisons in Gilis et al. are made between the cisapride monohydrate and cisapride tartrate formulations, and there is no disclosure that enhanced oral bioavailability is attributable to any micronization.

The disclosure on particle size in Gilis et al. at Col. 5, starting on line 32, states that "tablets or capsules according to the invention comprise salt forms of cisapride, preferably cisapride(L)–tartrate which are preferable in microfine or micronized form for some uses." Emphasis added. Further, Col. 5, starting on line 51, Gilis et al. states that in some cases for instance, when direct compressing of tablets is desired, "it may be useful to use coarser material (than the micronized or microfine material) of the presently described salts of cisapride." Thus, Gilis et al. does not disclose only micronized particles of salts of cisapride but also discloses coarser particles of salt forms of cisapride. The disclosure in Gilis et al. about particle size is related to tabletting problems and not bioavailability problems. Also, col. 6 of Gilis et al. discloses that formulations of micronized material have 50 % of particles which may have diameter larger than 24 μm, and formulations of coarser material have 50 % of particles which may have diameter larger than 50 μm.

There is no guidance or teaching how to modify Scaife et al. with Gilis et al. to obtain the present invention. A person of ordinary skill in the art reading Gilis et al. would not have known

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whether to use micronized particles or coarser particles and use of particular particle size or know how to prepare any other solubility improved form of metaxalone to obtain a pharmaceutical composition of metaxalone having enhanced oral bioavailability. It is clear from above that Gilis et al. does not teach the preparation of a "pharmaceutically acceptable solubility-improved form of metaxalone" including reducing particle size of metaxalone to affect its bioavailability. Even if the examiner were to cite another reference on a specific drug whose bioavailability was enhanced by reducing particle size, it would not be apparent or obvious to a person of skill in the art that the same would occur with metaxalone. Even if given such hypothetical prior art, there would be no reasonable expectation that metaxalone in a pharmaceutically acceptable solubility-improved form (e.g., micronized metaxalone) would have enhanced oral bioavailability, i.e., both increased rate as well as extent of absorption, as compared to the pharmaceutical composition of metaxalone corresponding to New Drug Application No. 13-217 when they are administered to a patient on an empty stomach.

Bioavailability as referred to in the specification means both the rate and extent to which the active ingredient is absorbed into the systemic circulation from the pharmaceutical composition.

However, whether it is in fact possible to obtain such an enhancement of both rate and extent of absorption of a particular drug cannot be predicted. In other words, if for example one micronized drug shows improved bioavailability, it does not naturally extend or be extrapolated to metaxalone.

For example, "Remington's Pharmaceutical Sciences", 18th Edition, Mack Publishing Company, Easton, Pennsylvania, 1990, page 1437 (a copy of which is concurrently submitted in a Supplemental Information Disclosure Statement) discusses the effect of particle size reduction of drugs on bioavailability, provides the following:

> Increased bioavailability with particle-size reduction also has been observed with griseofulvin. The extent of absorption of an oral dose increased 2.5 times when the surface area was increased approximately sixfold. Micronized griseofulvin permits a 50% decrease in dosage to obtain a satisfactory clinical response.

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> On the other hand, it was found that with nitrofurantoin there was an optimal average particle size that minimized side effects without affecting therapeutic response. In fact, a commercial product containing large particles is available. For chloramphenicol, particle size has virtually no effect on total absorption but it significantly affects the rate of appearance of peak blood levels of the drug.

Therefore, different results are obtained with different drugs and a person of skill in the art would not be motivated to reduce the particle size of metaxalone with a reasonable expectation of success that both rate and extent of absorption of metaxalone will be improved when given on an empty stomach.

A person of skill in the art is aware that reduction in particle size can have undesirable effect on drugs. See "Remington's Pharmaceutical Sciences", 18th Edition, Mack Publishing Company, Easton, Pennsylvania, 1990, pp 1437 which recites as below:

> Particle-size reduction may be deleterious for some drug substances. Increasing surface area by milling or other methods may lead to rapid degradation of a compound. Drug substances also may undergo polymorphic transformation during the milling process.
>
> ***
>
> Reduction of particle size also may create adverse responses. For example, fine particles of the prodrug trichloroethyl carbonate were more toxic in mice than regular and coarse particles.

The Gilis reference does not provide support for the rejection. The Examiner points to Gilis' teaching of micronization, and from this contends that it would have been obvious that a micronized form of metaxalone would have enhanced bioavailability on an empty stomach.

Even a cursory reading of Gilis demonstrates that the Examiner's conclusion is not supportable. Of course, one fundamental problem with the rejection is that Gilis is directed towards a different drug -- cisapride, not metaxalone. The pharmaceutical arts are not predictable, and it is settled that it is improper to expect that the teachings of one reference in the pharmaceutical arts may be applied to another.

Even if it were possible to overlook this deficiency, the rejection would still not follow from a combination of Scaife with Gilis. Gilis starts out by referring to several prior art attempts to improve the bioavailability of cisapride (see generally col. 1-3). After reporting that these efforts were unsatisfactory, Gilis teaches to provide cisapride in one of several salt forms -- sulfuric, L-tartaric. D-tartaric, or citric (see col. 4, lines 7-15).

Gilis then teaches that "[i]n some cases it may be useful to use a coarser material (than the micronized or microfine material) of the presently described salts of cisapride." Col. 5, lines 51 *et seq.* This is because, when the material is too fine, "there may arise problems with producing tablets," and "the tablets show low assay values." *Id.* These teachings are in accord with the other references cited above that indicating that there is no correlation between reduced particle size and bioavailability in the unpredictable pharmaceutical arts. *Accord,* MPEP 2164.03, noting predictabable factors, such as mechanical or electrical elements, and **unpredictable** factors, such as most chemical reactions and **physiological activity**.

Thus, the skilled artisan would be led by Gilis to conclude that it is very difficult to enhance the bioavailability of cisapride (as is evident from Gilis' description of the failed efforts of prior art workers in the field). The skilled artisan would then be led to conclude that particle size is not critical, and in fact that particles that are too small can have "problems" and "low assay values." Gilis purports to solve the bioavailability problem by providing a sulfate, tartrate, or citrate salt. The skilled artisan would find no metaxalone-related guidance whatsoever from these teachings. Gilis' teachings to this effect are specific to cisapride. Of course, beyond all of this, the skilled artisan would somehow have to get past the fact that Scaife teaches away from use of any other form of metaxalone besides the conventional form. There is simply no reasonable expectation of success provided in the teachings of Scaife and Gilis for a particular form of metaxalone when dosed on an empty stomach over that of the commercially available form Skelaxin®.

When rejecting a patent application as obvious based on multiple prior art references, the PTO must articulate the motivations for selecting references and combining them together. The motivation-suggestion-teaching test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in

the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims. *In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006).

Additionally, there is no motivation to combine the Gilis and Scaife references. The Office Action's position that citation of Gilis et al. in Scaife et al. is a motivation to combine the two is not correct and the Office Action does not provide support from case law in support of this position. The motivation should be derived from the prior art themselves or from the general knowledge of a person of skill in the art. Even if it is assumed that Examiner's position is correct, it is amply explained herein that obviousness does not flow from a combination of the cited references taken together with general knowledge of a person of skill in the art because they do not provide each and every feature of the invention.

Scaife et al. investigates effect of food on bioavailability of metaxalone and expressly teaches that bioavailability of metaxalone increases when administered with food. One of ordinary skill in the art would not be motivated to go in an opposite direction of Scaife et al.'s teachings and expect to achieve enhanced bioavailability in a pharmaceutically acceptable solubility-improved form as compared to the composition of Scaife et al. when they are administered to a patient on an empty stomach.

The secondary reference Gilis et al. teaches a pharmaceutical composition comprising a certain salt form of cisapride for the treatment of a gastrointestinal disorder without a drug food interaction. As explained above, Gilis et al. in no way suggests that metaxalone in a pharmaceutical composition of present invention would lead to the unexpected result of enhanced bioavailability of metaxalone even when administered without food.

The Office Action rejected applicant's explanation that reliance on Cheng et al. is not proper on the basis that Cheng et al. is cited by Scaife et al. The Office Action, however, presents no supporting case law for this position. In fact the first requirement is that the prior art must disclose at least one element of the claimed invention. Cheng et al. does not do that. Cheng et al. does not disclose any metaxalone composition with enhanced bioavailability or any method for enhancing bioavailability of metaxalone. Cheng et al. does not disclose any drug composition per se with enhanced bioavailability.

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Please refer to Table 1 in column 9 of Cheng et al. The AUC values are only a fraction of the reference product, meaning that the bioavailability is actually decreased rather than enhanced. Example 1 in Table 1 has no absorption enhancer. Examples 2 and 3 of Table 1 have sodium lauryl sulphate as the absorption enhancer, however, in spite of that the ratio of AUC and therefore the bioavailability in comparison to AUC for Glucophage®, the reference product (Test/Reference ratio of AUC) was less than 1.

Because Scaife et al. and Gilis et al., or Scaife et al. and Cheng et al. singly or combined, do not teach or suggest each and every feature recited in the amended claims, the claimed invention is novel and non-obvious in view of the prior art. Accordingly, applicants respectfully request that the prior art rejections be withdrawn.

Conclusion

In view of the foregoing, it is respectfully submitted that the pending claims are in condition for allowance. The Examiner is invited to contact the undersigned should it be deemed helpful to facilitate prosecution of the application.

Respectfully submitted,
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